P30416.A03

1



IFW

Application No. 10/588,286

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Yasukata DEKISHIMA et al.

Group Art Unit: 1632

Appln. No.

10/588,286

Examiner: Unassigned

(U.S. National Stage entry of PCT/JP05/02093)

I.A. Filed

: February 4, 2005

Confirmation No.: 6444

For

: METHOD FOR PRODUCING ALCOHOL AND CARBOXYLIC ACID

HAVING OPTICAL ACTIVITY

## INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop <u>Amendment</u>
Randolph Building
401 Dulany Street
Alexandria, VA 22314

Sir:

Pursuant to 37 C.F.R. § 1.56 and 37 C.F.R. §§ 1.97-1.98, Applicants hereby direct the Examiner's attention to the following information, which includes documents cited in the International Search Report, the International Preliminary Report on Patentability, and the Written Opinion for International Application No. PCT/JP05/02093, of which the above-referenced application is a National Stage:

- (1) S. XIE et al., "NAD<sup>+</sup>-Dependent (S)-Specific Secondary Alcohol Dehydrogenase Involved in Stereoinversion of 3-Pentyn-2-ol Catalyzed by *Nocardia fusca* AKU 2123", Biosci. Biotechnol. Biochem., Vol. 63, No. 10, pp. 1721-1729 (1999);
- (2) H. GROGER et al., "Preparative Asymmetric Reduction of Ketones in a Biphasic Medium with an (S)-Alcohol Dehydrogenase under in Situ-Cofactor-Recycling with a Formate Dehydrogenase", Tetrahedron, Vol. 60, No. 3, pp. 633-640 (2004);

- (3) W. HUMMEL et al., "Towards a Large-Scale Asymmetric Reduction Process with Isolated Enzymes: Expression of an (S)-Alcohol Dehydrogenase in E. coli and Studies on the Synthetic Potential of this Biocatalyst", Adv. Synth. Catal., Vol. 345, Nos. 1 and 2, pp. 153-159 (2003);
- (4) JP 2005-6552 A, January 13, 2005, accompanied by an English language abstract provided by esp@cenet;
- (5) JP 2005-2 A, January 6, 2005, accompanied by an English language abstract provided by esp@cenet
- (6) U.S. Patent No. 7,083,962 B2 (KIMOTO et al.), issued August 1, 2006; Applicants note that this document is identified by esp@cenet as a U.S. family member of document (5).

Furthermore, Applicants direct the Examiner's attention to the following documents cited and discussed in the specification of the present application:

- (7) A. SCHMITZER et al., "Reactivity at the Interface of Chiral Amphiphilic Dendrimers. High Asymmetric Reduction by NaBH<sub>4</sub> of Various Prochiral Ketones", J. Am. Chem. Soc., Vol. 123, pp. 5956-5961 (2001); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 1, last paragraph;
- (8) JP 11-240894 A, September 7, 1999, accompanied by an English language abstract provided by Patent Abstracts of Japan; Applicants note that this document is cited and discussed in the specification of the present application beginning at page 1, last paragraph;
- (9) JP 10-4998 A, January 13, 1998, accompanied by an English language abstract provided by Patent Abstracts of Japan; Applicants note that this document is cited and discussed in the specification of the present application beginning at page 2, line 5;

- (10) K. NAKAMURA et al., "Recent Developments in Asymmetric Reduction of Ketones with Biocatalysts", Tetrahedron: Asymmetry, Vol.14, pp. 2659-2681 (2003); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 2, line 11;
- (11) WO 00/24358 A1, May 4, 2000; Applicants note that this document is cited and discussed in the specification of the present application beginning at page 2, line 23;
- (12) JP 62-265279 A, November 18, 1987, accompanied by an English language abstract provided by Patent Abstracts of Japan; Applicants note that this document is cited and discussed in the specification of the present application beginning at page 2, last line;
- (13) U.S. Patent No. 4,775,692 (OHNO et al.), issued October 4, 1988; Applicants note that this document is identified by esp@cenet as a U.S. family member of document (12);
- (14) J. CASON et al., "Branched-Chain Fatty Acids. XVI. Synthesis of the Optical Isomers of 15-Methyloctadecanoic Acid", J.Am.Chem.Soc., Vol. 72, pp. 4695-4697; Applicants note that this document is cited and discussed in the specification of the present application beginning at page 3, line 2;
- (15) J. MALTHÊTE et al., "Reentrant Cholesteric Phase in Pure Compounds", Nouveau Journal de Chimie, Vol. 9, pp. 557-560 (1985); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 3, line 11;
- (16) W. THOMPSON et al., "3'-Tetrahydrofuranylglycine as a Novel, Unnatural Amino Acid Surrogate for Asparagine in the Design of Inhibitors of the HIV Protease", J. Am. Chem. Soc., Vol. 115, pp. 801-803 (1993); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 3, line 10;

- (17) T. OKANO et al., "Synthesis of Optically Active Trifluoromethylated Indolizidine Derivatives via Stereoselective Radical Cyclization", Organic Letters, Vol. 4, No. 9, pp. 1571-1573 (2002); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 3, line 19;
- (18) P. CONFALONE et al., "Intramolecular [3+2] Cycloaddition Routes to Carbon-Bridged Dibenzocycloheptanes and Dibenzazepines", J. Org. Chem., Vol. 48, pp. 2994-2997 (1983); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 3, line 26;
- (19) A. ALEXAKIS et al., "Asymmetric Conjugate Addition to Alkylidene Malonates", Tetrahedron: *Asymmetry*, Vol. 12, pp. 1151-1157 (2001); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 4, line 14;
- (20) W. OPPOLZER et al., "25. Camphorsulfonamide-Shielded, Asymmetric 1,4-Additions and Enolate Alkylations; Synthesis of a Southern Corn Rootworm Pheromone", Helvetica Chimica Acta, Vol. 68, pp. 212-215 (1985); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 4, line 20;
- (21) U.S. Patent No. 5,136,020 (MURTIASHAW), issued August 4, 1992; Applicants note that this document is cited and discussed in the specification of the present application beginning at page 5, line 4;
- (22) K. MORI, "Absolute Configuration of (-)-4-Methylheptan-3-ol, a Pheromone of the Smaller European Elm Bark Beetle, as Determined by the Synthesis of its (3R,4R)-(+)- and (3S,4R)-(+)-Isomers", Tetrahedron, Vol. 33, pp. 289-294 (1977); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 5, line 4;

(23) R. HILL et al., "Stereospecificity of Enzymatic Dehydrogenation during Tiglate Biosynthesis", J. Am. Chem. Soc., Vol. 102, pp. 7344-7348 (1980); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 5, line 18;

- (24) M. ZOLLER et al., "Oligonucleotide-directed Mutagenesis using M13-derived Vectors: an Efficient and General Procedure for the Production of Point Mutations in any Fragment of DNA", Nucleic Acids Research, Vol. 10, No. 20, pp. 6487-6500 (1982); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 23, line 15;
- (25) A. DIAMOND et al., "Methods of RNA Sequence Analysis", Methods in Enzymology, Vol. 100, pp. 431-453 (1983); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 23, line 15:
- (26) T. CLACKSON et al., "General Applications of PCR to Gene Cloning and Manipulation", Molecular Cloning, PCR-A Practical Approach, IRL Press, pp. 187-214 (1991); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 23, line 16;
- (27) J. REISER et al., "Transfer and Expression of Heterologous Genes in Yeasts Other than *Saccharomyces cerevisiae*", Advances in Biochemical Engineering and Biotechnology, Vol. 43, pp. 75-102 (1990); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 25, line 15;
- (28) M. ROMANOS et al., "Foreign Gene Expression in Yeast: a Review", Yeast, Vol. 8, pp. 423-488 (1992); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 25, line 15;

- (29) M. BAGDASARIAN et al., "Activity of the Hybrid trp-lac(tac) Promoter of Escherichia coli in Pseudomonas putida. Construction of Broad-Host-Range, Controlled-Expression Vectors", Gene, Vol. 26, pp. 273-282 (1983); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 27, line 4;
- (30) K. MIWA et al., "Construction of Novel Shuttle Vectors and a Cosmid Vector for the Glutamic Acid-Producing Bacteria *Brevibacterium lactofermentum* and *Corynebacterium glutamicum*", Gene, Vol. 39, pp. 281-286 (1985); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 27, line 6;
- (31) JP 57-183799 A, November 12, 1982, accompanied by an English language abstract provided by Patent Abstract of Japan; Applicants note that this document is cited and discussed in the specification of the present application beginning at page 27, line 11;
- (32) U.S. Patent No. 4,500,640 (KATSUMATA et al.), issued February 19, 1985; Applicants note that this document is identified by esp@cenet as a U.S. family member of document (31);
- (33) A. OZAKI et al., "Functional Expression of the Genes of Escherichia coli in Gram-Positive *Corynebacterium glutamicum*", Mol. Gen. Genet., Vol. 196, pp. 175-178 (1984); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 27, line 11;
- (34) W.-D. HEYER et al., "Replicating Plasmids in *Schizosaccharomyces pombe*: Improvement of Symmetric Segregation by a New Genetic Element", Molecular and Cellular Biology, Vol. 6, No. 1, pp. 80-89 (1986); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 27; line 19;

- (35) G SAUNDERS et al., "Heterologous Gene Expression in Filamentous Fungi", Trends in Biotechnology, Vol. 7, pp. 283-287 (1989); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 27, line 25; and
- (36) S. MAEDA et al., "Production of Human α-Interferon in Silkworm Using a Baculovirus Vector", Nature, Vol. 315, pp. 592-594 (1985); Applicants note that this document is cited and discussed in the specification of the present application beginning at page 28, line 4.

Copies of the above-listed documents (with the exception of the U.S. Patents), the International Search Report (in English and Japanese), the International Preliminary Report on Patentability, and the Written Opinion (in English and Japanese) for International Application No. PCT/JP05/02093 are enclosed together with a completed copy of the PTO-1449 Form listing these documents. Accordingly, the Examiner is requested to consider these documents and to indicate such consideration by returning a signed and initialed copy of the PTO-1449 Form with the next official communication.

Further to the U.S. Patent and Trademark Office's decision to partially waive the requirements under 37 C.F.R. § 1.98 (a)(2)(i) and (iii), copies of the U.S. Patents cited above are not enclosed herewith. However, if any copies are needed, the Examiner is respectfully requested to contact the undersigned.

Applicant notes that an Office Action on the merits has not yet issued in the instant application, and thus, no fee is necessary to ensure consideration of this statement. However, if an Office Action has issued and is crossing in the mail with this statement, the Patent and Trademark Office is hereby authorized to charge Deposit Account No. 19-0089 any fee necessary to ensure consideration of the submitted materials.

## P30416.A03

## Application No. 10/588,286

If there should be any questions, the Examiner is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted, Yasukata DEKISHIMA et al.

Bruce H. Bernstein

Reg. No. 29,027

August 3, 2007 GREENBLUM & BERNSTEIN, P.L.C. 1950 Roland Clarke Place Reston, VA 20191 (703) 716-1191 Stephen M. Roylance Reg. No. 31,296

P30416.p25									She	et 1 of 3					
FORM PTO-1	449		U.S. Department of Commerce Patent and Trademark Office			et No.	Application No. 108588,286								
OTRE	2	ATION DISCLOSURE STAT BY APPLICANT	Applicant Yasukata DEKISHIMA et al.												
AUG 1 5 20		Use several sheets if necessary		Filing Date February 4,	2005	Group 1632									
THE STATE OF THE S	U.S. PATENT DOCUMENTS														
EXAMPADEM INITIAL		DOCUMENT NUMBER	DATE	]	NAME	CLASS	SUBCLASS		FILING DATE IF APPROPRIATE						
!			]												
•			FOREIGN PATI	ENT DOCU	MENTS		•								
		DOCUMENT NUMBER	DATE	COU	NTRY	CLASS	SUBCLASS		TRANSI YES	LATION NO					
		OTHER DOCUMEN	NTS (Including A	uthor, Title	, Date, Pertinen	t Pages, Etc.)	٠								
	1	S. XIE et al., "NAD <sup>+</sup> -Dependent (S)-Specific Secondary Alcohol Dehydrogenase Involved in Stereoinversion of 3-Pentyn-2-ol Catalyzed by <i>Nocardia fusca</i> AKU 2123", Biosci. Biotechnol. Biochem., Vol. 63, No. 10, pp. 1721-1729 (1999).													
	2	H. GROGER et al., "Preparative Asymmetric Reduction of Ketones in a Biphasic Medium with an (S)-Alcohol Dehydrogenase under in Situ-Cofactor-Recycling with a Formate Dehydrogenase", Tetrahedron, Vol. 60, No. 3, pp. 633-640 (2004).													
	3	W. HUMMEL et al., "Towards a Large-Scale Asymmetric Reduction Process with Isolated Enzymes: Expression of an (S)-Alcohol Dehydrogenase in E. coli and Studies on the Synthetic Potential of this													

Biocatalyst", Adv. Synth. Catal., Vol. 345, Nos. 1 and 2, pp. 153-159 (2003). 4 A. SCHMITZER et al., "Reactivity at the Interface of Chiral Amphiphilic Dendrimers. High Asymmetric Reduction by NaBH<sub>4</sub> of Various Prochiral Ketones", J. Am. Chem. Soc., Vol. 123, pp. 5956-5961 (2001). K. NAKAMURA et al., "Recent Developments in Asymmetric Reduction of Ketones with Biocatalysts", 5 Tetrahedron: Asymmetry, Vol.14, pp. 2659-2681 (2003). 6 J. CASON et al., "Branched-Chain Fatty Acids. XVI. Synthesis of the Optical Isomers of 15-Methyloctadecanoic Acid", J.Am.Chem.Soc., Vol. 72, pp. 4695-4697. 7 J. MALTHÊTE et al., "Reentrant Cholesteric Phase in Pure Compounds", Nouveau Journal de Chimie, Vol. 9, pp. 557-560 (1985). W. THOMPSON et al., "3'-Tetrahydrofuranylglycine as a Novel, Unnatural Amino Acid Surrogate for 8 Asparagine in the Design of Inhibitors of the HIV Protease", J. Am. Chem. Soc., Vol. 115, pp. 801-803 (1993).9 T. OKANO et al., "Synthesis of Optically Active Trifluoromethylated Indolizidine Derivatives via Stereoselective Radical Cyclization", Organic Letters, Vol. 4, No. 9, pp. 1571-1573 (2002). P. CONFALONE et al., "Intramolecular [3+2] Cycloaddition Routes to Dibenzocycloheptanes and Dibenzazepines", J. Org. Chem., Vol. 48, pp. 2994-2997 (1983); 10 Carbon-Bridged A. ALEXAKIS et al., "Asymmetric Conjugate Addition to Alkylidene Malonates", Tetrahedron: Asymmetry, 11 Vol. 12, pp. 1151-1157 (2001). W. OPPOLZER et al., "25. Camphorsulfonamide-Shielded, Asymmetric 1,4-Additions and Enolate 12 Alkylations; Synthesis of a Southern Corn Rootworm Pheromone", Helvetica Chimica Acta, Vol. 68, pp. 212-215 (1985). 13 K. MORI, "Absolute Configuration of (-)-4-Methylheptan-3-ol, a Pheromone of the Smaller European Elm Bark Beetle, as Determined by the Synthesis of its (3R,4R)-(+)- and (3S,4R)-(+)-Isomers", Tetrahedron, Vol. 33, pp. 289-294 (1977).

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

**DATE CONSIDERED** 

**EXAMINER** 



. •														
FORM PTO-	1449		partment of Co and Trademar		Atty. Doci P31416	ket No.		Application No. 108588,286						
	INFORM	IATION DISCLOSURE STAT BY APPLICANT	Applicant Yasukata DEKISHIMA et al.											
	(	Use several sheets if necessary	Filing Dat February		Group 1632									
			U.S. PATENT	DOCUMI	ENTS			<u> </u>	20.1					
EXAMINER INITIAL		DOCUMENT NUMBER	DATE	,	NAME	SUBCLASS		FILING DATE IF APPROPRIATE						
			FOREIGN PATE	ENT DOCL	MENTS	<del></del>								
		DOCUMENT NUMBER	DATE	COU	INTRY	CLASS	SUB	CLASS YES		ATION NO				
		OTHER DOCUMEN	JTS (Including A	uthon Title	Data Partin	ant Pages Eta								
	14	·						ocyntheci	s" I Am (	~hem				
	14	R. HILL et al., "Stereospecificity of Enzymatic Dehydrogenation during Tiglate Biosynthesis", J. Am. Chem. Soc., Vol. 102, pp. 7344-7348 (1980).												
	15	M. ZOLLER et al., "Oligonucleotide-directed Mutagenesis using M13-derived Vectors: an Efficient and General Procedure for the Production of Point Mutations in any Fragment of DNA", Nucleic Acids Research, Vol. 10, No. 20, pp. 6487-6500 (1982).												
	16	A. DIAMOND et al., "Methods of RNA Sequence Analysis", Methods in Enzymology, Vol. 100, pp. 431-453 (1983).												
	17	T. CLACKSON et al., "General Applications of PCR to Gene Cloning and Manipulation", Molecular Cloning, PCR-A Practical Approach, IRL Press, pp. 187-214 (1991).												
	18	J. REISER et al., "Transfer and Expression of Heterologous Genes in Yeasts Other than Saccharomyces cerevisiae", Advances in Biochemical Engineering and Biotechnology, Vol. 43, pp. 75-102 (1990).												
	19	M. ROMANOS et al., "Foreign Gene Expression in Yeast: a Review", Yeast, Vol. 8, pp. 423-488 (1992).												
	20	M. BAGDASARIAN et al., "Activity of the Hybrid trp-lac(tac) Promoter of Escherichia coli in Pseudomonas putida. Construction of Broad-Host-Range, Controlled-Expression Vectors", Gene, Vol. 26, pp. 273-282 (1983).												
	21	K. MIWA et al., "Construction of Novel Shuttle Vectors and a Cosmid Vector for the Glutamic Acid-Producing Bacteria Brevibacterium lactofermentum and Corynebacterium glutamicum", Gene, Vol. 39, pp. 281-286 (1985).												
	22	A. OZAKI et al., "Functional Expression of the Genes of Escherichia coli in Gram-Positive Corynebacterium glutamicum", Mol. Gen. Genet., Vol. 196, pp. 175-178 (1984).												
	23	WD. HEYER et al., "Replicating Plasmids in <i>Schizosaccharomyces pombe</i> : Improvement of Symmetric Segregation by a New Genetic Element", Molecular and Cellular Biology, Vol. 6, No. 1, pp. 80-89 (1986).												
	24	G SAUNDERS et al., "Heter 7, pp. 283-287 (1989).	ologous Gene	Expressi	on in Filame	entous Fungi	", Trer	nds in Bio	technology	, Vol.				
	25	S. MAEDA et al., "Product Vol. 315, pp. 592-594 (1985)		α-Interfe	eron in Silk	worm Using	a Bac	culovirus	Vector", N	ature,				
	26	English language abstract of	JP 2005-6552.			****								

\*EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

DATE CONSIDERED

English language abstract of JP 2005-02 A.

English language abstract of JP 11-240894.

EXAMINER

27 28 FORM PTO-1449

.....

U.S. Department of Commerce Patent and Trademark Office Atty. Docket No. P31416

Application No. 108588,286

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

BY APPLICANT
(Use several sheets if necessary)

Applicant Yasukata DEKISHIMA et al.

Filing Date February 4, 2005 Group 1632

									February 4, 20			4, 2003	005 1632				
									U.S. PATE	NT DOCUME	ENTS		16				
EXAMINER INITIAL			DOCUMENT NUMBER						DATE		NAME	CLASS	SU	BCLASS	FILING DATE IF APPROPRIATE		
						08/01/06	KIMOTO										
		4	7	7	5	6	9	2	10/04/88	OHNO et	al.						
		5	1	3	6	0	2	0	08/04/92	MURTIA	ASHAW						
		4	5	0	0	6	4	0	02/19/85		MATA et a	al.					
														-			
	I	Т							FOREIGN PA	TENT BOCK	MENTS	Τ			TDANI	CL ATION	
			DO	сим	ENT	NUM	BER		DATE	cou	COUNTRY		SUBCLASS		TRANSLATION YES NO		
	2005	-	_		6	5	5	2	01/13/05	JAPAN							
	2005	_						2	01/06/05	JAPAN							
	11	-	2	4	0	8	9	4	09/07/99	JAPAN							
	10	_			4	9	9	8	0113/98	JAPAN							
	00	/		2	4	3	5	8	05/04/00	W.I.P.O							
	62	-	2	6	5	2	7	9	11/18/87	JAPAN							
	57	-	1	8	3	7	9	9	11/12/82	JAPAN							
		-															
		-															
							,										
	20	T F.	1:1							Author, Title	, Date, Perti	nent Pages, Etc.	)				
	30	English language abstract of JP 11-4898.  English language abstract of JP 62-265279.  English language abstract of JP 57-183799.															
	31																
XAMINER									<del></del>	DA	TE CONSIDE	ERED					

Include copy of this form with next communication to applicant.